

OFFICE OF RESEARCH INTEGRITY

AN INTRODUCTION

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Office of the Assistant Secretary for Health
Office of Research Integrity
Rockville, MD 20852

Office of Research Integrity: An Introduction

Background

Scientific misconduct became a public issue in the United States in 1981 when then Representative Albert Gore, Jr., chairman of the Investigations and Oversight Subcommittee of the House Science and Technology Committee, held the first hearing on the emerging problem. The hearing was prompted by the public disclosure of scientific misconduct cases at four major research centers in 1980. Some twelve cases of scientific misconduct were disclosed in this country between 1974-1981. Congressional attention to scientific misconduct was maintained throughout the 1980s by additional allegations of scientific misconduct and reports that the National Institutes of Health (NIH), universities, and other research institutions were inadequately responding to those allegations.

Congress took action in 1985 by passing the Health Research Extension Act. The Act, in part, added Section 493 to the Public Health Service (PHS) Act. Section 493 required the Secretary of the Department of Health and Human Services (HHS) to issue a regulation requiring applicant or awardee institutions to establish "an administrative process to review reports of scientific fraud" and "report to the Secretary any investigation of alleged scientific fraud which appears substantial." The Section also required the Director, NIH, to establish a process for receiving and responding to reports from institutions. This legislation complemented existing authority under which the PHS pursued scientific misconduct in the 1970s and early 1980s. Guidelines were published in the *NIH Guide for Grants and Contracts* in July, 1986; the Final Rule, "Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science", was published in the *Federal Register* on August 8, 1989. This regulation is codified at 42 CFR Part 50, Subpart A.

Before 1986, reports of scientific misconduct were received by funding institutes within PHS agencies. In 1986, the NIH assigned responsibility for receiving and responding to reports of scientific misconduct to its Institutional Liaison Office. This was the first step taken to create a central locus of responsibility for scientific misconduct within the Department of Health and Human Services. In March 1989, the PHS created the Office of Scientific Integrity (OSI) in the Office of the Director, NIH, and the Office of Scientific Integrity Review (OSIR) in the Office of the Assistant Secretary for Health (OASH). The sole purpose of these offices was to deal with scientific misconduct; the creation of OSIR also began the process of removing responsibility for scientific misconduct from the funding agencies. In May 1992, OSI and OSIR were consolidated into the Office of Research Integrity (ORI) in the OASH. In June 1993, the process of removing responsibility for handling allegations of scientific misconduct from the funding agencies was completed when President Clinton signed the NIH Revitalization Act of 1993. This Act established the ORI as an independent entity within the Department of Health and Human Services reporting to the Secretary of Health and Human Services.

The ORI oversees and directs the PHS research integrity efforts with the exception of the regulatory research activities of the Food and Drug Administration. The PHS is composed of the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Substance Abuse and Mental Health Services Administration, the Health Resources and Services Administration, the Agency for Health Care Policy and Research, the Agency for Toxic Substances and Disease Registry, and the Indian Health Service.

ORI Functions

The Office of Research Integrity is responsible for protecting the integrity of PHS extramural and intramural research programs. (Extramural programs provide funding to research institutions that are not part of the Federal government. Intramural programs provide funding for research conducted within Federal government facilities).

In 1992, the PHS provided \$7.5 billion to support 31,289 extramural research grants awarded to 2,213 institutions.

ORI carries out its responsibility by (1) developing and promulgating policies, procedures, rules and regulations; (2) administering an assurances program; (3) reviewing investigations conducted by applicant or awardee institutions; (4) conducting investigations at applicant or awardee institutions and in the PHS intramural research programs; (5) presenting misconduct findings in administrative hearings before the HHS Departmental Appeals Board (DAB); and (6) promoting scientific integrity.

Develop Policies, Procedures, and Regulations

The ORI is responsible for developing policies, procedures, rules, and regulations for responding to allegations of scientific misconduct occurring in research supported by the PHS extramural and intramural research programs. These policies, procedures, rules, and regulations cover wide spectrum of subjects: Definitions, the investigative process, the protection of complainants, the rights of the respondent, reporting requirements, appeal procedures, implementation of administrative actions, standards of proof, records management, and public disclosure of information. For instance, the Federal regulation previously cited defines misconduct or misconduct in science as

“... fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.”

The Division of Policy and Education is responsible for developing policies, procedures, and regulations related to the handling of allegations of scientific misconduct.

Administers an Assurances Program

The ORI administers an Assurances Program mandated by Federal regulation. The Federal regulation requires each institution that applies for or receives support under the PHS Act to file an assurance with ORI that it has established an administrative process for receiving, reviewing, investigating, and reporting allegations of misconduct; that this administrative process meets the requirements of the Federal regulation, and that it will comply with this administrative process when responding to allegations of scientific misconduct. In addition, each institution must submit annually aggregate information on allegations received and inquiries conducted.

In administering the Assurances Program, the ORI determines whether an institution has a current assurance on file, checks the administrative processes to see whether they comply with the Federal regulation, reviews inquiries and investigations conducted by the institution to determine whether they comply with the administrative process and the Federal regulation, and institutes compliance actions when violations are detected.

The Assurances Program is part of the Division of Policy and Education.

Reviews Institutional Investigations

Because institutions have the primary responsibility for responding to allegations of scientific misconduct, the ORI role in most investigations is usually that of reviewing the institution's investigative report. Responding to an allegation of scientific misconduct involves a two-step process: An inquiry, and if necessary, an investigation. An inquiry is a preliminary examination of an allegation to determine whether the allegation has sufficient substance to warrant an investigation. The Federal regulation requires institutions to conduct an inquiry immediately upon receipt of an allegation. Complainants usually make their allegations to the institution employing the respondent although allegations may be made directly to ORI. In such cases, ORI normally asks the institution to conduct an inquiry. The inquiry should be completed in 60 days. An investigation is a formal examination of an allegation to determine whether misconduct has occurred, who engaged in misconduct, and the extent of the misconduct. An institution must begin an investigation within 30 days of completing an inquiry. The institution must submit its investigative report to ORI within 120 days of initiating the investigation.

The ORI generally does not review inquiries because an institution is required neither to inform ORI that an inquiry is underway nor to submit a report at its conclusion. The ORI

reviews inquiry reports under three conditions: (1) The ORI requested the institution to conduct the inquiry because the allegation was made directly to the ORI, (2) the ORI had reason to believe that the institution did not conduct the inquiry properly, or (3) the institution submitted the inquiry report to ORI as part of the report of an investigation.

The ORI reviews all investigations. Institutions must inform the ORI when they begin an investigation and submit a report at its conclusion. To be within ORI's jurisdiction, the alleged misconduct must normally involve PHS-supported research or an application for PHS support, and fall within the PHS definition of scientific misconduct. If these requirements are fulfilled, the ORI reviews the case to determine whether the investigation was thorough, fair, and objective and whether the evidence supports the findings. At this point, the ORI may accept or reject the findings, ask for additional information, request further investigation, or begin its own investigation.

The ORI reviews all inquiries conducted by PHS agencies in response to allegations of scientific misconduct in PHS intramural research programs.

The Division of Research Investigations is responsible for reviewing inquiries and investigations into allegations of scientific misconduct.

Conducts Investigations

The primary responsibility for conducting an investigation rests with the institution, but the ORI will conduct its own investigation when requested by an institution, when the institution is unwilling or unable to conduct an investigation, when an institution refuses to provide requested information or perform additional investigation, or when the institutional investigation is insufficient. When conducting an investigation, ORI usually seeks the assistance of two or more scientists to ensure that the necessary expertise is available.

The ORI conducts all investigations of scientific misconduct in PHS intramural research programs.

Individuals found to have committed scientific misconduct by an institution or the ORI are included in the PHS ALERT system. This is a Privacy Act system of records which is intended to inform, only on a need-to-know basis, PHS agency personnel relevant to the implementation of administrative actions.

The Division of Research Investigations conducts investigations into allegations of scientific misconduct in PHS extramural and intramural research programs. The PHS ALERT system is maintained by the Assurances Program within the Division of Policy and Education.

Presents Misconduct Findings in the Hearing Process

When the ORI concludes a case, it notifies respondents of its findings. In cases in which misconduct is found, respondents are informed that they have 30 days to request a hearing before the Departmental Appeals board (DAB) on the findings and proposed administrative actions. During a hearing, respondents have an opportunity to be represented by counsel, to question any evidence and witnesses presented by ORI, and to present evidence and witnesses in rebuttal to the findings and proposed administrative actions. Once the DAB has heard both the ORI and the respondent, the DAB then makes its decision. This decision is the final PHS decision.

The Research Integrity Branch, Office of the General Counsel, represents the ORI in hearings before the DAB.

Promotes Research Integrity

Besides investigating allegations of scientific misconduct, the ORI works to reduce the incidence of misconduct by promoting research integrity in collaboration with universities, medical schools, and scientific and professional societies. Research integrity is promoted through a quarterly newsletter and other publications, workshops and conferences, courses on research ethics, the development of guidelines, and analytical and policy studies.

The Division of Policy and Education is primarily responsible for developing activities aimed at promoting research integrity within PHS extramural and intramural research programs.

Frequently Asked Questions

How can someone report possible misconduct in science?

The primary responsibility for responding to allegations of scientific misconduct rests with the applicant or awardee institution. Each of these institutions must, as a condition of funding, establish an administrative process for handling allegations of scientific misconduct. This administrative process should clearly state how allegations of scientific misconduct are to be made at that institution. However, if the complainant does not wish to make the allegation to the designated official at the institution, he or she may contact the Division of Research Investigations, ORI, directly. The address and phone numbers for ORI are listed below.

What constitutes a good investigation?

A good investigation is characterized by (1) clearly stated allegations, (2) interviews with all persons who may have pertinent information, (3) timely sequestration of any data in

question, (4) thorough review of all relevant documentation and research data, (5) findings supported by documentation, (6) an objective and knowledgeable investigative team, (7) a well-organized and clearly written report, (8) comments from the respondent and complainant on the report, and (9) maintenance of confidentiality.

What administrative actions can be imposed on researchers found to have committed scientific misconduct?

Researchers found guilty of scientific misconduct are subject to administrative actions imposed by their institutions and the Department of Health and Human Services. In some cases, the researcher resigns or is dismissed. Institutions also may deny or revoke tenure, withdraw principal investigator status, issue letters of reprimand, review applications more stringently, or require withdrawal of manuscripts and correction of the literature. Government actions may include debarment from Federal funding, prohibition from service on PHS advisory committees, institutional certification of the accuracy of the respondent's applications, and supervision of the respondent's research.

Address and Phone Numbers:

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